

*Study Title*

**Analysis of the Initially Isolated Formulation of the PMN Substance  
Required Under Consent Order PMN P-11-91: Analysis for Change in  
Manufacture of the Initially Isolated Formulation**

**AUTHOR:**

**DATE OF REPORT: October 12, 2016**

**PERFORMING LABORATORY:**

**LABORATORY PROJECT ID:**

**SPONSOR:**

## Table of Contents

Objective .....	3
Materials and Methods.....	3
A. Samples Analyzed.....	3
1. Initially Isolated Formulation of the PMN Substance .....	3
B. Analytical Methods .....	4
1. Analytical Method for Initially Isolated Formulation.....	4
Results and Discussion .....	4
A. Analysis of the Initially Isolated Formulation .....	4
Conclusion .....	4

## Objective

The subject consent order requires the Company to analyze representative samples of the initially isolated formulations of the PMN substance at each manufacturing facility for the analytes specified in Table 3 of the consent order and report the results at initial commencement of manufacture or import and again if any new manufacturing facility is added or if the process of manufacture of the PMN substance or any intermediate thereof is significantly altered. The Company is also required to annually analyze the initially isolated formulations and report these results to EPA, in a cycle complementary to the

This report presents results of analyses conducted after a change in manufacturing location for an initially isolated formulation of the PMN substance under PMN P-11-91 Subsequent analyses required by the Consent Order will be submitted at the intervals specified by the Consent Order.

## Materials and Methods

### A. Samples Analyzed

#### 1. Initially Isolated Formulation of the PMN Substance

The first lot of this initially isolated formulation of the PMN substance after manufacturing location change was packed out on August 15<sup>th</sup>, 2016 and designated

As per the Consent Order for PMN P-11-91, the formulation was analyzed for the substances specified in Table 3 of the Consent Order.

## B. Analytical Methods

### 1. Analytical Method for Initially Isolated Formulation

were quantified i by using methods described in detail in a previously submitted report (Report number P-10-16-01).

## Results and Discussion

### A. Analysis of the Initially Isolated Formulation

The results for analytes specified in Table 3 of the Consent Order are presented below:

Analyte	CAS Number	Estimated Maximum in the Initially Isolated Formulation of the PMN Substance	Measured in the Initially Isolated Formulation of the PMN Substance

## Conclusion

The analyses specified in Consent Order P-11-91 for manufacture of a new initially isolated formulation of the PMN substance after change to manufacturing process have been completed.